

**REMARKS**

Claims 1-16 are still on file.

Claims 1 and 9 have been amended to clarify the concept of respiratory system and to provide sufficient antecedent basis.

Claims 8 and 16 have been amended to remove their multiple dependencies.

Claims 1-3 and 9-11 are rejected by the Examiner under 35 USC 102(e) as being anticipated by Bathe *et al.*. In his rejection, the Examiner states that, in Bathe *et al.* system, "the concentration may vary from injection to injection". It is respectfully submitted that nothing in Bathe *et al.* indicates that the concentration of the gaseous substance injected varies from injection to injection. At least for this reason, it is respectfully submitted that claims 1-3 and 9-11 are not anticipated by Bathe *et al.*.

The Examiner also rejects claims 4-7 and 12-15 as being unpatentable over Bathe *et al.* in view of Dietz. As discussed hereinabove, the applicant fails to see where Bathe *et al.* discuss the variation of concentration from one injection to another. It is therefore respectfully submitted that since the primary reference lacks at least an element of the claimed invention, its combination with a secondary reference, also devoid of this element, can not render the dependent claims obvious.

It should be understood that claim amendments for which no explanation is established above were made for clarity purposes only and not for reasons related to statutory requirements for patentability.

No new subject matter has been added to the claims. The amendments to the claims are fully supported by the specifications as originally filed.

It is therefore respectfully submitted that the present application is in condition for allowance and a notification to this effect is solicited.

Respectfully submitted,

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## MARKED UP CLAIMS



The claims have been amended as follows. Underlines indicate insertions and ~~strikeouts~~ indicate deletions.

Claim 1 (amended). An injection system for the delivery of a gaseous substance from a container to a patient pulmonary respiratory system through a conduit coupled to the patient pulmonary respiratory system; said injection system comprising:

a control unit controlling said injection system;

a valve assembly in connection with the conduit to selectively allow [the] delivery of the gaseous substance from the container to the conduit; said valve assembly including a valve and valve actuating means allowing variable opening of said valve; said valve actuating means being coupled to said control unit to be controlled thereby; and

a flowmeter quantitatively measuring inspiratory gas flow in the conduit; said flowmeter being coupled to said control unit to supply inspiratory gas flow data thereto;

wherein a) said control unit controls said valve assembly so that said variable opening of said valve is responsive to said inspiratory gas flow in the conduit so as to achieve a predetermined concentration of the gaseous substance with respect to the inspiratory gas, and b) said predetermined concentration varies within a plurality of inspiratory phases of the patient.

Claim 8 (amended). An injection system as recited in ~~claims~~ claim 1, ~~2, 3, 4, 5, 6 or 7~~, wherein said gaseous substance includes nitric oxide.

Claim 9 (amended). An injection system for the delivery of a gaseous substance from a container to a patient pulmonary respiratory system through a conduit coupled to the patient pulmonary respiratory system; the pulmonary respiratory system of the patient being also coupled to a ventilator forcing inspiratory gas therein; said injection system comprising:

a control unit controlling said injection system; said control unit receiving inspiratory gas flow data from the ventilator; and

a valve assembly in connection with the conduit to selectively allow [the] delivery of the gaseous substance from the container to the conduit; said valve assembly including a valve and valve actuating means allowing variable opening of said valve; said valve actuating means being coupled to said control unit to be controlled thereby;

wherein a) said control unit controls said valve assembly so that said variable opening of said valve is responsive to said inspiratory gas flow supplied to the patient so as to achieve a predetermined concentration of the gaseous substance with respect to the inspiratory gas, and b) said predetermined concentration varies within a plurality of inspiratory phases of the patient.

Claim 16 (amended). An injection system as recited in ~~claims claim~~ claim 9, ~~10, 11, 12, 13, 14 or 15~~, wherein said gaseous substance includes nitric oxide.